

## **REMARKS**

### **Claim Rejections 35 U.S.C. § 112**

The Examiner has rejected independent Claims 1 and 9, and the related dependent claims 3 and 11, under 35 USC §112, second paragraph, as being indefinite. Specifically, the Examiner states that the previous amendment, which introduced the term “fixed position,” renders the claims confusing and contradicting since the claims also require that the occlusion member is releasably connected to the elongate member. Applicant responds that the term “fixed” was not intended to connote a permanent attachment, but rather that the location where the occlusion member is located on the elongate member is specific, as opposed to being able to freely slide along a length of the elongate member. This language was introduced to more clearly differentiate the Kensey reference discussed in the previous response. To address the Examiner’s concerns, Applicant now amends the claims to substitute the term “specific” for “fixed.”

In light of this amendment, Applicant respectfully requests that the Examiner withdraw the §112 rejection of Claims 1, 3, 9 and 11.

### **Claim Rejections 35 U.S.C. § 102**

The Examiner has rejected pending Claims 1, 3, 9 and 11 under 35 USC §102(b) as being anticipated by the newly cited reference Cragg et al. (USPN 5,782,861.) The Examiner contends that Cragg discloses each limitation of the claims, including an elongate member having a distal opening in its distal region and a proximal opening in its proximal region which are connected by a lumen in which “the elongate member is capable of performing the functions as claimed.”

As described in the specification, Applicant respectfully submits that the purpose of the distal and proximal openings is to provide a “bleed back” function that indicates when the occlusion member has been advanced into a blood vessel lumen of the patient. One of skill in the art will appreciate that the desired function occurs when the occlusion member is fully inserted within the blood vessel lumen. These aspects of the invention are reflected in the claim language which requires that the occlusion member be located distal to the distal opening and

also requires that blood entering the distal opening flows through the elongate member and exits the proximal opening, so that it is visible outside the patient.

In contrast, the structure disclosed by Cragg does not share these characteristics and is not capable of operating in the desired manner claimed. The Examiner has indicated that tubular shaft 38 corresponds to the claimed elongate member. Similarly, the Examiner relates “distal end portion” 40 to the occlusion member. As shown in Fig. 8 of the Cragg reference, for example, distal end portion 40 is seamlessly connected tubular shaft 38. Furthermore, the only distal opening of tubular shaft 38 is covered or continued by distal end portion 40. Therefore, any blood entering such a distal opening must first flow through distal end portion 40. This relationship means that blood could flow through distal end portion 40 and into tubular shaft 38 as soon as any part of distal end portion 40 was exposed to the blood vessel lumen. Accordingly, any “bleed back” indication on the Cragg device would not signal that distal end portion 40 was entirely disposed within the lumen of the patient. Applicant also notes that Cragg provides no suggestion to use or modify the device, as the lumen of tubular shaft 38 is completely occluded by guide wire 36 (as shown in Fig. 1, for example). Thus, blood would not be able to flow from the distal end of tubular shaft 38 to the proximal end when used as disclosed by Cragg.

Applicant’s device, on the other hand, provides a bleed back indication only when the entire occlusion member is positioned within the blood lumen. As described in the specification and shown in the figures, the distal opening of Applicant’s devices is not covered and is not otherwise in fluid communication with the occlusion member. Blood from the patient’s lumen enters the distal opening directly, not via the occlusion member. Therefore, since the distal opening is located proximal to occlusion member, blood entering the distal opening and exiting the proximal opening is a positive signal that the occlusion member is fully inserted into the blood vessel lumen.

To emphasize these aspects of the invention, Applicant has amended the independent claims to clarify that blood does not pass through the occlusion member. Since the Cragg reference clearly does not disclose a device having these characteristics, Applicant respectfully

requests that the Examiner reconsider and withdraw the §102 rejection of Claims 1, 3, 9 and 11 over Cragg.

**Rejoinder of Claims 5 and 7**

As discussed in the previous responses, Applicant requests that method Claims 5 and 7 be rejoined, as they have been amended to share all the structural limitations of the product claims discussed above.

**Conclusion**

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. The Examiner is encouraged to call the undersigned collect at (415) 705-6377 if there are any outstanding issues or questions which can be resolved to allow this application to be passed to issue.

Respectfully submitted,

DERGOSITS & NOAH LLP

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By: /Todd A. Noah/  
Todd A. Noah  
Reg. No. 35,626